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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,271	05/04/2001	Steven M. Ruben	PF526	7683

22195 7590 12/12/2003

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EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/848,271	RUBEN ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *20 October 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *33-38*.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' amendments to claims 33 and 36 to include the step of comparing binding to an individual not suffering from Sjogren's disease have been entered since they clarify the claimed methods, however the claims are still rejected under 35 U.S.C. 112, second paragraph because as stated in the previous office action, it is not "altered" binding that would be detected by the polypeptide of SEQ ID NO: 2, but "increased" binding, since post-filing date references teach that patients with Sjogren's disease have increased levels of neutrokine-alpha. In the art, altered binding encompasses a change in affinity of binding between two molecules, and there is no support for this in the specification as filed. Applicants' arguments that given the nexus between the function of TR18 (binding neutrokine-alpha), the expression of TR18 on B cells, that it was known at the time of filing that neutrokine-alpha was known to enhance B-cell proliferation and to enhance immunoglobulin production, and that it was known at the time of filing that patients suffering from autoimmune diseases such as Sjogren's disease exhibit increased levels of autoreactive antibodies, one of skill in the art would have been able to routinely use the compositions of the present invention in the detection of Sjogren's disease, have been fully considered but not deemed persuasive. At the time of filing, it was not known that patients with Sjogren's disease have elevated levels of neutrokine-alpha. On page 128 of the specification, lines 20-22, the specification states that "an individual having an autoimmune disease or disorder may express aberrantly high levels of neutrokine-alpha, APRIL, and/or TR18 when compared to an individual not having an immune disease or disorder." This statement shows a lack of conception of what the expression levels of any of theses compounds were in individuals with autoimmune diseases, and additionally, this statement also encompasses all of the other numerous autoimmune diseases listed on page 127, line 26 to page 127, line 19, for example, and not just Sjogren's disease. Patients suffering from those other autoimmune disorders also exhibit increased levels of autoreactive antibodies and possibly also exhibit high levels of neutrokine-alpha. If increased binding of TR18 was detected in a sample from a patient suspected of having an autoimmune disorder compared to a sample from a normal individual, this would not be diagnostic of a specific disorder; the patient could be suffering from any one of those disorders listed. Therefore, the utility of the method of diagnosing Sjogren's disease using TR18 protein was not readily available at the time of filing, and the rejection under 35 U.S.C. 112, first paragraph for lack of utility, is maintained.